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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,477	06/22/2001	Arnold J. Reuser	24512-X	6846

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EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	9

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/886,477	Applicant(s) REUSER ET AL.	
	Examiner Thaian N. Ton	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 22, 36 and 37, drawn to methods of purifying human acid alpha glucosidase from a sample containing human acid alpha glucosidase by anion exchange or affinity chromatography, classified in class 436, subclass 161, for example.

II. Claims 1-19, 22, 29-35, drawn to methods of purifying human acid alpha glucosidase from a sample containing human acid alpha glucosidase, wherein the sample is milk produced by a transgenic mammal expressing the alpha-glucosidase, and methods of purifying a heterologous protein from the milk of a transgenic animal, classified in class 436, subclass 161, class 800, subclasses 4, 7, for example.

III. Claims 20 and 21, drawn to human acid alpha-glucosidase, classified in class 424, subclass 94.1+, for example.

IV. Claims 23-28, drawn to methods of treating a patient deficient in endogenous alpha-glucosidase by administration of human acid alpha-glucosidase, and a pharmaceutical composition comprising human acid alpha-glucosidase, classified in class 514, subclass 2, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and either of Inventions II or IV are mutually exclusive and independent. The methods of purifying human acid alpha glucosidase from a sample containing human acid alpha glucosidase by anion exchange or affinity chromatography of Invention I are not required for the implementation of the methods of purifying human acid alpha glucosidase from a sample containing human acid alpha glucosidase, wherein the sample is milk produced by a transgenic

mammal expressing the alpha-glucosidase, and methods of purifying a heterologous protein from the milk of a transgenic animal of Invention II and the methods of treating a patient deficient in endogenous alpha-glucosidase by administration of human acid alpha-glucosidase, and a pharmaceutical composition comprising human acid alpha-glucosidase of Invention IV, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol and different technical considerations.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the human acid alpha-glucosidase can be purified from transfected bacteria.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the human acid alpha glucosidase can be purified from transfected bacteria.

Inventions II and IV are mutually exclusive and independent. The methods of purifying human acid alpha glucosidase from a sample containing human acid

alpha glucosidase, wherein the sample is milk produced by a transgenic mammal expressing the alpha-glucosidase, and methods of purifying a heterologous protein from the milk of a transgenic animal of Invention II are not required for the implementation of the methods of treating a patient deficient in endogenous alpha-glucosidase by administration of human acid alpha-glucosidase, and a pharmaceutical composition comprising human acid alpha-glucosidase of Invention IV, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol and different technical considerations.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case human acid alpha-glucosidase can be used in affinity chromatography.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703)872-9306.

Deborah Crouch

DEBORAH CROUCH
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GROUP 1800 /1630

TNT

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